

THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue of:	:	Primary Examiner: Suzanne E. McDowell
Letters Patent 6,316,520	:	Issue Date: November 13, 2001
Inventor: Ihab Hekal	:	Group Art Unit: 1732
Serial No.: 09/157,032	:	
Filed: September 18, 1998	:	
For: Monolithic Polymer Composition	:	
Having A Releasing Material	:	

Mail Stop Reissue
P. O. Box 1450
Commissioner for Patents
Alexandria, VA 22313-1450

EV316897266US

REISSUE DECLARATION BY INVENTOR AND POWER OF ATTORNEY

Sir:

As a below named sole inventor, I hereby declare that:

- I. My residence, post office address and citizenship are stated below next to my name.
- II. I believe I am the original, sole and first inventor of the subject matter which is described and claimed in U.S. Patent No. 6,316,520 (The '520 patent") granted on November 13, 2001, and for which a reissue patent is sought.
- III. I have reviewed and understand the content of the 520 patent, including the claims as filed in this reissue.
- IV. I acknowledge the duty to disclose information known to me which is material to patentability as defined in 37 C.F.R. §§ 1.56 and 1.75(a)(7).
- V. All errors corrected by this reissue application up to the time of filing this oath or declaration under 37 C.F.R. §1.175 occurred without any deceptive intent on the part or the applicant.
- VI. I verily believe the 520 patent to be partially inoperative by reason of me failing to claim more or less than I had a right to claim in the patent. In one example, the 520 patent claims include at least one error that causes the issued claims to be too narrow. The specification discloses, at column 5, line 12, the broad category of "biologically active ingredients" but, yet the issued claims fail to recite this broad category of

“biologically active ingredients.” As such, the issued claims of the 520 patent are partially inoperative by reason of me failing to claim this broad category of “biologically active ingredients” for which I had a right to claim in the patent.

VII. I believe that this Reissue Application seeks to correct the above-described errors through the following changes:

Add new claims 37 through 60:

37 (new). An article of manufacture comprising a monolithic composition comprising at least the following components:
a water-insoluble polymer;
a releasing material selected from the group consisting of biologically active ingredients, wherein the releasing material is composed of a particle and the particle is at least about 10% by weight of the polymer;
an agent that acts as a transmission bridge between an exterior of the polymer and the interiorly located releasing material, wherein the affinity between the agent and the releasing material is greater than between the polymer and the releasing material; and
wherein the composition comprises an interconnecting channel composed of the agent.

38 (new). An article of manufacture comprising a monolithic composition comprising at least the following components:
a water- insoluble polymer;
a releasing material selected from the group consisting of antimicrobials, wherein the releasing material is composed of a particle and the particle is at least about 10% by weight of the polymer;
an agent that acts as a transmission bridge between an exterior of the polymer and the interiorly located releasing material, wherein the affinity between the agent and the releasing material is greater than between the polymer and the releasing material; and
wherein the composition comprises an interconnecting channel composed of the agent.

39 (new). An article of manufacture comprising a monolithic composition comprising at least the following components:
a water-insoluble polymer;
a releasing material selected from the group consisting of aromatic medicines, wherein the releasing material is composed of a particle and the particle is at least about 10% by weight of the polymer;
an agent that acts as a transmission bridge between an exterior of the polymer and the interiorly located releasing material, wherein an affinity between the agent and the releasing material is greater than between the polymer and the releasing material; and
wherein the composition comprises an interconnecting channel composed of the agent.

40 (new). The article of manufacture of claim 37, wherein at least the agent is heated above its melt point in combination with the polymer and the releasing material.

41 (new). The article of manufacture of claim 38, wherein at least the agent is heated above its melt point in combination with the polymer and the releasing material.

42 (new). The article of manufacture of claim 39, wherein at least the agent is heated above its melt point in combination with the polymer and the releasing material.

43 (new). The article of manufacture of claim 37, wherein the agent is hydrophilic.

44 (new). The article of manufacture of claim 38, wherein the agent is hydrophilic.

45 (new). The article of manufacture of claim 39, wherein the agent is hydrophilic.

46 (new). The article of manufacture of claim 37, wherein the releasing material is at least 10% to about 60% by weight of the polymer.

47 (new). The article of manufacture of claim 38, wherein the releasing material is at least 10% to about 60% by weight of the polymer.

48 (new). The article of manufacture of claim 39, wherein the releasing material is at least 10% to about 60% by weight of the polymer.

49 (new). An article of manufacture comprising a monolithic composition formed by combining at least the following components:

- a water-insoluble polymer;

- a releasing material selected from the group consisting of biologically active ingredients, wherein the releasing material is composed of a particle and the particle is at least about 10% by weight of the polymer;

- an agent that controls the transmission between an exterior of the polymer and the interiorly located releasing material, wherein an affinity between the agent and the releasing material is greater than between the polymer and the releasing material; and

- wherein the composition comprises an interconnecting channel composed of the agent.

50 (new). An article of manufacture comprising a monolithic composition formed by combining at least the following components:

- a water-insoluble polymer;

- a releasing material selected from the group consisting of antimicrobials, wherein the releasing material is composed of a particle and the particle is at least about 10% by weight of the polymer;

an agent that controls the transmission between an exterior of the polymer and the interiorly located releasing material, wherein an affinity between the agent and the releasing material is greater than between the polymer and the releasing material; and wherein the composition comprises an interconnecting channel composed of the agent.

51 (new). An article of manufacture comprising a monolithic composition formed by combining at least the following components:

a water-insoluble polymer;

a releasing material selected from the group consisting of aromatic medicines, wherein the releasing material is composed of a particle and the particle is at least about 10% by weight of the polymer;

an agent that controls the transmission between an exterior of the polymer and the interiorly located releasing material, wherein an affinity between the agent and the releasing material is greater than between the polymer and the releasing material; and wherein the composition comprises an interconnecting channel composed of the agent.

52 (new). The article of manufacture of claim 49, wherein at least the agent is heated above its melt point in combination with the polymer and the releasing material.

53 (new). The article of manufacture of claim 50, wherein at least the agent is heated above its melt point in combination with the polymer and the releasing material.

54 (new). The article of manufacture of claim 51, wherein at least the agent is heated above its melt point in combination with the polymer and the releasing material.

55 (new). The article of manufacture of claim 49, wherein the agent is hydrophilic.

56 (new). The article of manufacture of claim 50, wherein the agent is hydrophilic.

57 (new). The article of manufacture of claim 51, wherein the agent is hydrophilic.

58 (new). The article of manufacture of claim 49, wherein the releasing material is at least 10% to about 60% by weight of the polymer.

59 (new). The article of manufacture of claim 50, wherein the releasing material is at least 10% to about 60% by weight of the polymer.

60 (new). The article of manufacture of claim 51, wherein the releasing material is at least 10% to about 60% by weight of the polymer.

VIII. I believe that the invention as claimed in this Reissue Application was disclosed in the Patent, and no new matter has been introduced in this Reissue Application. The amendment to the claims are fully supported by the original filed specification.

Specifically, the following are examples of the support:

- a) "a water insoluble polymer" – col. 4, lines 5-6; col. 4, lines 11-12;
- b) "a releasing material selected from the group consisting of" a) "biologically active ingredients" – col. 5, lines 11-12; b) "antimicrobials" – col. 5, line 13; and c) "aromatic medicines" – col. 5, line 13.
- c) "an agent that acts as a transmission bridge between an exterior of the polymer and the interiorly located absorbing and releasing material" – col. 4, lines 28-30; col. 6, lines 1-4; col. 7, line 65 – col. 8, line 1;
- d) "an agent that controls the transmission between an exterior of the polymer and the interiorly located releasing material" – abstract; and col. 2, lines 37-38;
- e) "the releasing material is composed of a particle and the particle is at least about 10% by weight of the polymer" – col. 5, line 54; col. 6, lines 16-19;
- f) "the between the agent and the releasing material is greater than between the polymer and the releasing material" – col. 5, lines 62-67; and
- g) "interconnecting channel composed of the agent" – col. 7, line 64 – col. 8, line 1.

The recitation of "biologically active ingredients" are known in the art as compositions comprising compounds including, but not limited to, anti-restinosis compounds, proteins, nucleic acids, polysaccharides and synthetic organic molecules, having a bioactive effect, for example, anesthetics, vaccines, chemotherapeutic agents, hormones, pain killers, metabolites, sugars, immunomodulators, antioxidants, ion channel regulators, and antibiotics, in vivo diagnostic agents (e.g., contrast agents), vitamins, toxin antidotes, anti-inflammatory agents, and medications useful for renal procedures such as dialysis (e.g., heparin).

It also known that "biologically active ingredients" can also be composed of a composition comprising compounds having bioactive activity with a biocompatible polymer matrix -- either biodegradable and non-biodegradable. Examples of biodegradable polymer matrix include synthetic and natural polymers. Examples of synthetic polymers include polyanhydrides, polyhydroxyacids such as polylactic acid, polyglycolic acids and copolymers thereof, polyesters, polyamides, polyorthoesters, and some polyphosphazenes. Examples of naturally occurring polymers include proteins and polysaccharides such as collagen, hyaluronic acid, albumin and gelatin. The compound having bioactive activity can be encapsulated within, throughout, and/or on the surface of the implant. Examples of non-biodegradable polymers include Ethylene-vinyl acetate copolymer, polyurethanes, polyacrylonitriles, and some polyphosphazenes. Thus, for purposes of the present invention, a releasing material selected from the group consisting of biologically active ingredients includes a material that is composed of a composition comprising compounds having bioactive activity with a biocompatible polymer matrix.

As is also known in the art, the recitation of "biologically active ingredients" of "antimicrobials" include, but are not limited to, compounds having antimicrobial activity such as chlorhexidine, chlorhexidine digluconate, tetracycline, tobramycin and gentamicin.

IX. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and believe are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

X. I hereby specify the following as the correspondence address to which all communications about this application are to be directed:

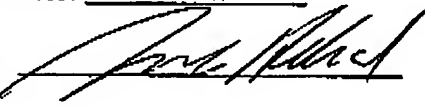
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THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Reissue of:	:	Primary Examiner: Jan H. Silbaugh
Letters Patent 6,316,520	:	Assistant Examiner: Suzanne E. McDowell
Inventor: Ihab Hekal	:	Group Art Unit: 1732
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PROOF OF OWNERSHIP OF ASSIGNEE

CSP Technologies, Inc., assignee of U.S. Patent 6,316,520 consents to the filing of this reissue of U.S. Patent No. 6,316,520.

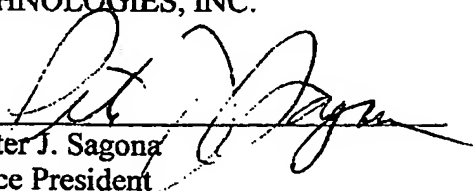
I, PETER J. SAGONA, also hereby state that I am authorized to sign on behalf of CSP Technologies, Inc. and to establish ownership of this case in accordance with 37 CFR 3.73(b)(ii) by declaring that U.S. Patent 6,316,520 (U.S. Serial No. 09/157,032) was assigned to Capitol Specialty Plastics, Inc. on May 28, 2002 and recorded under Reel/Frame 012916/0862. There was a subsequent change of name from Capitol Specialty Plastics, Inc. to CSP Technologies, Inc. recorded on June 23, 2003 under Reel/Frame 013751/0552.

Dated: 13 November 2003

Place: Conshohocken, Pennsylvania

CSP TECHNOLOGIES, INC.

By:


Peter J. Sagona
Vice President
Applications Development